MINUTES OF THE U.S. ENVIRONMENTAL PROTECTION AGENCY
SCIENCE ADVISORY BOARD
Drinking Water Committee Meeting
December 10-12, 2001
Embassy Suites LAX North Hotel
Los Angeles, CA 2004
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Purpose of the Meeting: The US Environmental Protection Agency Science Advisory Board's Drinking Water Committee met from December 10-12, 2001 in Los Angeles, California to consider certain issues associated with EPA's upcoming Stage 2 Disinfection/Disinfectant Byproduct Rule and their Long Term 2 Enhanced Surface Water Treatment Rule. The review was conducted by a Panel established from the Drinking Water Committee and a number of liaisons and consultants.

The meeting was announced in the Federal Register (FR 66, No. 8: pp. 56557; November 8, 2001–Attachment A). The panel roster for the meeting is in Attachment B. The charge to the Panel is found in Attachment C.

Summary of the Meeting

Monday, December 10, 2001

1. Opening Remarks

Dr. Trussell welcomed the panelists, agency and the public to the meeting and discussed the agenda and the structure of the meeting.

Mr. Thomas O. Miller, Designated Federal Officer for the Committee briefed the Panel on the structure of the Science Advisory Board, its practices, and the need for consideration of conflict-of-interest. He then asked the members to introduce themselves. The member's notes of introduction are contained in Attachment D. These notes provide information that each Panelist felt to be relevant about him/herself for the other Panelists, the Agency, and to public observers. Members introducing themselves at the beginning of the meeting included Drs. Rhodes Trussell, Gary Toranzos, Christine Moe, Ricardo De Leon, David Baker, Philip Singer, Mark Benjamin, Paul Boulos, Michael Daniels, Barbara Harper, Richard Bull, Mary Davis, Sidney Green, David Spath, Gregory Harrington, Charles O'Melia, and L.D. McMullen, while Drs. Lauren Zeise and Mark Berliner introduced themselves later in the meeting.

For the record, Dr. De Leon clarified that the patent he holds for a *Cryptosporidium* detection method is not approved by EPA. Dr. Moe added information on her research into transmission of infectious agents and the epidemiology of waterborne and food-borne disease;

and her grants from the EPA STAR program on endemic waterborne disease associated with groundwater and modeling community transmission of Norwalk virus. She also gets research funding from USDA ASPH-CDC cooperative agreement, the Thrasher Research Fund, the Centers for Disease Control, and the North Carolina Department of Health and Human Services. She has no DBP or *Cryptosporidium* research. Dr. O'Melia noted his past work on the SAB Environmental Engineering Committee, his work on an AWWA study of *Cryptosporidium* removal, work on an EPA-funded project dealing with natural organic matter removal in riverbank filtration, and an AWWARF study on the effectiveness of oxidants on filtration processes. Dr. O'Melia's university department also has funding from Videndi/US Filter for a graduate student to support research on membrane applications in water treatment. Dr. Spath noted his responsibilities for implementation of federal regulations in the state of California and their *Cryptosporidium* action plan. Dr. Harrington noted his research support from AWWA Research Foundation, NSF, Plymouth Products on *Cryptosporidium* removal, EPA on removal of waterborne pathogens, and the Wisconsin Consortium for Applied Water Quality Research on ultraviolet irradiation in drinking water treatment.

Dr. Trussell also asked members of the public to introduce themselves so that the Panel would be familiar with those observing. Members of the public are noted on the Sign-in Sheets at Attachment E2.

2. Summary of the Proceedings - Stage 2 Disinfectant/Disinfection Byproduct Rule-making Proposal (S2D/DBPR): Initial Distribution System Evaluation (IDSE) -- Deliberations of the Panel

Dr. Trussell introduced the topic and Committee's review approach which was to involve this period of deliberation in open session, development of written comments in public sessions in various breakout rooms, and then a debrief on day 3 of the final comments prepared at the meeting. Dr. Trussell noted that the Panel was asked to respond to EPA's Charge Question which asked *"if the Initial Distribution System Evaluation (IDSE) is capable of identifying new compliance monitoring points that target high TTHM/HAA5 levels and if it is the most appropriate tool to reach this objective?"*

Dr. Singer led the discussion for the subgroup that considered this charge question (which also included Drs. Baker, Boulos, Benjamin, McMullen, O' Melia, and Harrington). Dr. Singer had prepared a summary of his comments and this is Attachment F to these minutes. His comments focused on: a) issues with short-term temporal variability in regard to Initial Distribution System Evaluation site selection; b) the need to clarify that EPA's focus is on thrihalomethane 4 (TTHM4) as total trihalomethanes (TTHM) as opposed to a larger number that would be necessary to reflect our actual understanding of TTHMs today; c) a similar EPA focus on haloacetic acid 5 (HAA5) instead of HAA9; and d) whether the locational running annual average focused on acute, chronic, or both types of exposures.

Other points mentioned in the discussion by the full subgroup and the remaining members of the Panel included:

a) that the proposed sampling plan was resource driven and did not have the spatial and temporal design to obtain "optimum" results;
b) uncertainty may not be adequately dealt with in the sampling plan;
c) the plan lacks seasonal and daily variability;
d) existence of higher residuals is to mitigate microorganisms of concern–it's a tradeoff;
e) the number of samples to be taken;
f) SWAT was developed to predict treatment results more than distribution system changes – the problems with SWAT predictions that are caused by the variability in the ICR input data–the weakness is recognized by EPA but it is the best they had available;
g) the distribution of people along the distribution system;
h) the focus on classes that are not really accounting for all possibilities in the class – significant amounts of significant players are being missed;
i) IDSE guidance may be better for THMs than HAAs;
j) the possibility of building models from the bottom (specific systems) up to a national level;
k) the LRAA does away with the benefit of averaging across the system sites and water quality to determine compliance;
l) system hydraulics and its relation to water demands along the system;
m) the impact of switching to chloramines on resultant DBPs;
n) the dynamic nature of distribution systems themselves – growing areas have growing distribution systems which influence what occurs there; and the representativeness of samples taken at certain nodes for the whole system.

The ultimate question is, keeping monitoring costs reasonably constant, are we better off with stage 2 (LRAA & IDSE) than stage 1 with the RAA – it is likely that the IDSE and LRAA provide an improvement over the previous requirement. We probably are getting at the peaks better, but question is whether we are getting the highest?

The Panel discussion of the issue ended and a break was taken. Please refer to Attachment G for the written draft comments and conclusions on this topic.

Break

3. Long Term 2 Enhanced Surface Water Treatment Rule-making Proposal (LT2ESWTR): Microbial Risk Assessment Issues

NOTE: The meeting departed from the sequence in the published agenda at this point because one person critical to the Stage 2 health discussion was delayed in getting to the meeting. Therefore, the Chair exercised his discretion and initiated the LT2ESWTR risk discussion at this point.

Dr. Trussell introduced the topic and Committee's review approach for the topic. He noted that the Panel was asked to respond to EPA's Charge Question which *has requested SAB comment on pre-and post-LT2ESWTR Cryptosporidium risk assessment, that is, how EPA estimated the incidence of cryptosporidiosis attributed to drinking water prior to and after implementation of the LT2ESWTR.*

Dr. Moe led the discussion for the subgroup that considered this charge question (which also included Drs. De Leon and Toranzos. Dr. Moe noted that the reports provided by EPA were relatively well written. She noted the Subgroups lack of hands on expertise in conducting microbial risk assessments and suggested that EPA might want to get some who specialize in risk assessment to provide information on formal quantitative risk assessment procedures specifically. The subgroup chose to focus on the assumptions used in the agency analysis, transparency of the analysis, and whether evidence supporting the analysis and assumptions were sound.

Issues discussed by the subgroup and other Panelists included:

a) Infectivity of the various strains; is the UCP strain an outlier; use of PCR to determine infectivity; storage time related to infectivity; dose response across the strains; distribution and variability of the dose response; the priors used in the dose response analysis (via MCMC); asymptomatic infections and their relation to infectivity determination;
b) Mortality associated with the disease;
c) Oocyst viability identification (internal structure, amorphous, empty, etc.); survival in the environment;
d) Drinking water ingestion rates: source (report on the issue was reviewed by the SAB during 1999);
e) Strain genotypes; all studies are with genotype 2; no human data on genotype 1;
f) Host susceptibility; sensitive populations; and
g) Crypto susceptibility to treatment and the impact on disease rates.

The Panel discussion of the issue ended and a break was taken. Please refer to Attachment G for the written draft comments and conclusions on this topic.

Break for lunch

4. Stage 2Disinfectant/Disinfection Byproduct Rule-making Proposal: Health Concerns – Deliberations of the Panel

Dr. Trussell introduced the topic and Panel's review approach for the topic. He stated that EPA is concerned with reproductive, developmental, and carcinogenic effects which are associated with TTHMs and HAAs. The agency intends to reduce the variability of exposure to DBPs for people at different points in the distribution system and therefore reduce risks. He noted that the Panel was asked to respond to EPA's Charge Question which asked "*whether the health concerns associated with establishing the Locational Running Annual Average (LRAA) standard, in conjunction with the IDSE, are decreased in comparison to the health concerns in association with the existing Running Annual Average (RAA) standard."*

Dr. Davis led the discussion for the subgroup and the Panel (other members included Drs. Sidney Green, Barbara Harper, Richard Bull, David Spath, and Lauren Zeise). Dr. Davis

reminded the Panel that the IDSE subgroup noted the somewhat limited ability of the IDSE to in characterize DBPs in the distribution system, but that some decrease in exposure is expected. Decreased exposure should yield decreased risk. She also noted the reanalysis of the original Waller DBP study from California that is to be published this week. The study in some ways increases our concern for reproductive and developmental effects and in other ways does not. It is not clear how it should influence the analysis.

Other issues discussed by the subgroup and other Panelists included:

a) The link between the toxicology study and epidemiology study results with regard to THM's bladder cancer cause and effect relationship; the likelihood of other DBPs and the cause-effect relation to bladder cancer;
b) the growing linkage between toxicology and epidemiology outcomes for some HAAs in the area of reproductive and developmental studies;
c) the reality that there is a "soup" of DBPs in the system and how that might relate to measured DBPs in the regulation and those yet untargeted by name; treating for the wrong DBPs may not decrease risk in reality if they are not the ones actually causing risk; the existence of other health endpoints beyond bladder cancer that are a part of the rule's target;
d) how decreased DBP spikes relate to cancer risk; the relationship of risk decreases and exposure decreases for reproductive and developmental effects at low exposure levels;
e) the difficulty in quantifying the risk decrease from the data now available;
f) the need to discuss reproductive and developmental effects separately;
g) the continued need for research to identify the DBPs causing an effect;
h) the link of the proposed rule to risk equity for all on the water system; the rule decreases disproportionate exposure; the need to be up front in the documentation about this factor;
i) whether decreasing disinfection levels too far would decrease efficacy of microbial control; the need for risk-risk balancing across DBP risk and microbial risk; the higher probability of process upsets at lower safety factors in disinfection.

The Panel discussion of the issue ended and a break was taken. Please refer to Attachment G for the written draft comments and conclusions on this topic.

Break

5. Panel Work Group Session on S2D/DBPR and LT2ESTWTR questions discussed

The Subgroups that had conducted their deliberations during the day met in breakout locations to begin to draft their conclusions for use in the Panel report. Each breakout session was announced and conducted as a public session and those observing the proceedings attended the sessions they chose to attend. The sessions were to continue until 5:30 pm and then the day's meeting was adjourned until the following day.

Tuesday, December 11, 2001

8:30 The Chair reconvened the meeting

6. Long Term 2 Enhanced Surface Water Treatment Proposal (LT2ESWTR): *Cryptosporidium* Occurrence

Dr. Trussell introduced the topic. The rule will supplement the existing surface water treatment rule by establishing targeted treatment requirements for systems with greater vulnerability to *Cryptosporidium* (those with high source water pathogen levels/those that do not use filtration). EPA has requested SAB comment on how *EPA estimated Cryptosporidium occurrence in source and finished waters, especially the statistical techniques (Markov Chain Monte Carlo Analysis) that were used in the analysis*. Members of the Subgroup included Drs. Rhodes Trussell, Michael Daniels, and Mark Berliner.

The discussion focused on a number of topics, including:

a) Given the problems with data collection, the analysis is plausible; the basic structure is reasonable; the statistics should be viewed as a part of the full picture - however here we do not have the information to say that it all came together; the documents provided by EPA do not contain sufficient information to describe what the analysis involved;
b) Markov Chain Monte Carlo Analysis (MCMC) – justification for the *Cryptosporidium* log normality assumption for crypto occurrence data; how well the MCMC algorithms perform in sampling from posterior distributions for occurrence and infectivity;
c) Infectivity modeling – the lack of details are provided on the posterior distributions;
d) Data collection – the manner in which samples were collected at various sites; whether there is a concern that only 44% of plants had all 18 usable samples; representativeness of samples (e.g., seasonal); the answer may be in the data, that is, maybe the data set does not have what is needed to allow one to do the analysis and get the best answer; the Agency has gotten from the data as much as it can give given its quality; getting substantially better data from additional survey is unlikely;
e) Occurrence Modeling – robustness; seasonality; temporal correlation within a site; temporal variability across sites; relationship between turbidity and concentration; different models used from filtered to unfiltered plants;
f) Outbreaks – as constructed the proposal addresses endemic occurrence of disease; outbreaks are different situations and involve process problems; poor surveillance makes it difficult to detect outbreaks;

The Panel discussion of the issue ended and a break was taken. Please refer to Attachment G for the written draft comments and conclusions on this topic.

Break

7. Long Term 2 Enhanced Surface Water Treatment Proposal (LT2ESWTR): Microbial Treatment Issues

Dr. McMullen acted as Chair of the Panel for this session. Dr. Trussell conferred with the Statistics Subgroup, which met in a separate public break out session, to draft its comments during that time. Dr. McMullen introduced the topic. He noted that EPA *requested SAB comment on whether the proposed credits associated with four "microbial toolbox treatment techniques" discussed in the rule, are appropriate, based on the information provided."*

Dr. McMullen led the discussion for the Subgroup (other members of the Subgroup included Drs. Phil Singer, Charles O'Melia, Greg Harrington, and David Spath). Dr. McMullen commended EPA and the Stakeholder group for developing the bin classification system and the microbial toolbox. They add flexibility to attaining the rule's intent of safe drinking water.

The following tools were discussed:

a) Off Stream Storage
b) Pre-sedimentation
c) Lime Softening
d) Lower Finished Water Turbidity

The majority of the discussion centered around the actual use of each technique within the context of the overall treatment approach and whether the data provided support the full extent of the credits assigned for each of the tools.

The Panel also discussed the credits assigned to conventional filtration, noting that the proposed 3 log credit was a change from the previous 2 logs given. It was not clear why the change was made by EPA. The level assigned will have an influence on the binning system that is a part of the Stage 2 proposal.

The Panel discussion of the issue ended and a break was taken. Please refer to Attachment G for the written draft comments and conclusions on this topic.

Break

8. Panel Work Group Sessions on all matters (Toolbox group separate)

The Subgroups reconvened in their break out sessions to continue to draft their conclusions on each of the five Charge questions for use in the Panel report. Each breakout session was announced and conducted as a public session and those observing the proceedings attended the sessions they chose to attend. The sessions were to continue until 5:30 pm and then the day's meeting was adjourned until Wednesday morning.

Wednesday, December 12, 2001

9. Continue writing sessions

Time was made available for Subgroups to complete their drafting work in preparation for the report out session that was the main business for day 3.

10. Agency Debriefing

The Subgroups reconvened in Plenary session to report on their comments and conclusions in response to the charge questions. Each subgroup representative presented the groups conclusions. EPA representatives from the Office of Water were on the teleconference line while this debrief occurred. The sections below are the written comments that were presented at this session. They will be the starting point for the report to the Administrator.

a) Stage 2 DBP Health Subgroup; Dr. Barbara Harper

> Changing the regulation from the RAA to the LRAA would be expected to reduce variability slightly, but the major impact would be in reducing extremes of exposure. While we would expect some reduction in variability and possibly in the mean exposures at individual locations, the reduction in exposure is not expected to be large. For the high locations within a system as identified in the LRAA, the average exposure would be reduced in the households served by the LRAA locations. However, we do not know the numbers or characteristics of the population affected, which makes quantification of anticipated health benefits difficult. Still, the assurance that a larger proportion of the system will fall under the regulated concentration assures greater equity than achieved now.
>
> The Committee agrees that establishing a LRAA would be expected to reduce exposure to the compounds that are measured. As detailed elsewhere in this document, after discussion of the dynamics of water movement through the distribution system and on-going production and degradation of disinfection by-products, there is serious doubt that the requirements of the IDSE will result in a sufficiently complete distribution system characterization to be confident that the variability of exposure will actually be reduced. The extent to which controlling the LRAA for the TTHMs and HHAs reduces risk requires that there be similar decreases of the causative agent for each of the health concerns of interest. Additionally, achieving further reduction in a specific risk assumes that the current exposure is above a threshold, if thresholds exist for the particular health effect.
>
> Assessments of benefits have emphasized reductions in bladder cancer risk, rightfully because lifetime consumption of chlorinated surface water poses a bladder cancer risk of order 10-3. There are other serious health effects associated with exposures to specific disinfection byproducts. These include risks of other cancers, impairment of male and

female reproduction, and effects on developing on developing organisms (this will be laid out in more detail). For systems that make minor adjustments in their current treatment technologies to achieve the requirements of the LRAA, reduction of DBP exposures will provide additional protection against the occurrence of these outcomes.

The impact of adopting the LRAA method on DBP constituents that cause human bladder cancer is not currently known or quantifiable. While there is compelling evidence that lifetime consumption of chlorinated surface water poses a bladder cancer risk, the causative constituents have not been identified. In laboratory animals several THMs and HAAs exhibit carcinogenic potential, but the evidence that they explain the bladder cancer risk is lacking. There are other disinfectant by-products that are not halogenated which are potent carcinogens (e.g. nitrosamines) whose concentrations might be increased by certain methods proposed for controlling the regulated DBPs (e.g. use of chloramine as opposed to free chlorine in disinfection). Undoubtedly, reductions in THMs and HAAs would be paralleled by reductions in other halogenated compounds, for example HANs, halogenated aldehydes and ketones and halogenated furanones such as MX. The measured compounds within the THM and HAA classes may or may not be valid surrogates for the compounds that produce bladder cancer. These reductions are likely to reduce health risk but may not impact bladder cancer risk because the exposure to the agents causing bladder cancer may not be reduced. As a consequence, the committee cannot accept the assumption that reduction of THMs and HAAs will necessarily result in reductions in bladder cancer.

As pointed out in the Agency review, reproductive toxicities due to DBPs have not been as clearly established epidemiologically as bladder cancer has been. However, some members of the THMs, HAAs and HANs have been shown to produce reproductive and developmental toxicities. The measured compounds within the THM and HAA classes may or may not be valid surrogates for the compounds that produce reproductive toxicities.

It is recommended that the various toxicological effects be clearly separated in the report. As an example, reproductive effects are always presented as reproductive, developmental effects. This blending can lead to incorrect assumptions (one endpoint), and therefore inaccurate hazard and risk estimates. These effects more than likely occur by different mechanisms of action. Reproductive effects have been the major focus in this report, but one needs to recognize that by addressing reproductive effects, one does not necessarily address developmental. More specifically, developmental effects can occur in the absence of reproductive and the obverse is also true. Deriving a conclusion based on reproductive effects and incorrectly extrapolating that conclusion to developmental would be a major scientific and regulatory policy error.

It is suggested that there is more than adequate data to rationalize the regulation of individual disinfection by-products within the THM and HAA classes. Within each of these groups it is apparent that risks are not homogeneous across the individual compounds using conventional methods of calculating cancer slope factors or non-zero

MCLGs. The use of the TTHM and HAA5 disallows the calculation of benefits using customary and conventional means of assessing risk and benefits. This would seem to be a very important intermediate step to making the association between the totals measured within these classes and the benefits that might be realized from the regulation. In addition to the THMs and HAAs, there are data for other DBPs that are adequate for estimating risks (e.g., MX, chlorate).

A more credible scientific case could be made for the regulation by identifying the epidemiological associations seen with chlorination and using that to emphasize the seriousness of the problem. As the document demonstrates these risks are significantly greater than would be predicted from the toxicological data that focuses primarily on the THM and HAA classes. However, association of benefits with respect to endpoints such as bladder cancer from reducing TTHMs and HAAs cannot be proven and threatens to undercut the credibility of the proposed rule. The Committee would prefer that benefits attributed to reductions of THMs and HAAs be clearly identified with the health effects shown to be produced by these by-products. This would provide an estimate of the minimum benefit that might be expected. Then the Agency can lay claim to the possibility that these reductions would likely be greater if these measures were indeed good surrogates for that chemical or group of chemicals that produce the actual effect observed in human populations. This approach also serves to provide clear direction to deficiencies in the database that can be very directly addressed in the research program that is designed to resolve the issue.

Another difficulty is that various remedial actions will be more effective in reducing some members of the THM and HAA classes than others. For example, reduction of dissolved organic carbon (DOC) will reduce total THMs, but this will generally result in a greater reduction in chloroform concentrations than in the brominated THMs. The same argument is true of the HAA class. To the extent that brominated by-products are plausible causes of certain adverse outcomes (e.g. colon cancer and some reproductive effects), the reductions in risk may be considerably smaller than would be predicted by reductions of TTHMs and HAA5. Furthermore, HAA5 does not even address the DBP that appears to be the reproductive toxicant of most potency that has been examined to date (bromochloroacetic acid). Careful consideration of these factors could substantially reduce the calculated benefit of changing the RAA to LRAA.
Despite the difficulties associated with associating precise estimates of benefits to the switch from the RAA approach to the LRAA approach, one should not lose sight of the fact that the latter approach provides a measure of equity not previously reflected in the standards for disinfectant by-products. The LRAA allows one to state that a larger segment of the consumers of drinking water within a particular water system will meet the MCL than the RAA approach. The committee suggests that this issue be given much greater prominence in the argument supporting the LRAA than is the case in documentation presently available to the committee. The RAA across an entire system does not necessarily capture individual locations with consistently higher concentrations of DBPs. The intent of the LRAA rule is to identify locations likely to have higher baseline concentrations, and where spikes occur. Focusing the regulation on the highest

locations in the distribution system will reduce the number of households with high-end exposures. Although the benefits cannot be quantified at present, it is an indisputable fact that an increased level of protection in some of the most-exposed and most sensitive receptors will occur. It is still not clear whether the IDSE as described will identify locations with daily, weekly, seasonal or operational spikes; it is also not clear whether occasional spikes have a reproductive or developmental effect. Although monitoring would still be quarterly or less, the intent is specifically to reduce both intermittent spikes (acute) and high baseline (chronic) exposures, which are related to reproductive and developmental and cancer health effects, respectively. Since there are also other potential health benefits from reducing locations with consistently higher averages, and since the rule is tied to an upper tail exposure rather than to a median exposure, there are further gains in equity to be expected from implementing this rule.

b) Stage 2 DBP; **IDSE Effectiveness**; Dr. Phil Singer

The Drinking Water Committee of the Science Advisory Board believes that the proposed Initial Distribution System Evaluation is indeed capable of identifying new compliance monitoring points that target higher THM and HAA levels than are currently measured in the existing THM Rule and Stage 1 DBP Rule compliance monitoring programs. However, it may not identify the highest levels to which consumers in a given distribution system are exposed. The basis for the latter statement is that the IDSE does not consider short-term, temporal variations that occur at different sites in the distribution system due to varying (e.g. diurnal) water demands and distribution system architecture and operation. Distribution systems are, by their nature, highly dynamic. Varying water demand patterns (e.g. low density and high density residential water use, industrial and commercial water use, irrigation) and operating conditions (e.g. pumping patterns and storage tank operations) normally lead to appreciable temporal and spatial variations in hydraulic residence times (water age) and water quality throughout the system that are not captured by the proposed IDSE. Hence, it is unlikely that a single grab sample taken at any site at any time will yield a representative THM or HAA concentration for that site, and that grab samples taken at a number of sites are unlikely to identify sampling sites with the highest THM and HAA concentrations. This temporal variability needs to be acknowledged in the IDSE documentation.

Further, rates of DBP formation and degradation are temperature-dependent and may change on a seasonal basis. Coupling this with the fact that water demand patterns, and therefore hydraulic residence times, also may change with season may mean that peak HAA levels migrate from the remote parts of the system during colder months to interior portions of the system during warmer months.

Site selection must be re-evaluated periodically for several reasons. Fore example, rapidly growing utilities in which distribution system architecture and flow patterns may change correspondingly cause the sites with high THM and HAA levels to change. If sample locations are not changed with time to reflect these changes in the distribution system, then the sample locations may lose their relevance over time. Further, the IDSE

is a 12-month program, and utilities and primacy agencies have no assurances that the 12-month period over which the IDSE is performed will indeed be typical of normal system operations. EPA needs to provide guidance for this situation.

The EPA asks if the IDSE is the most appropriate tool to reach the objective of identifying new compliance monitoring points that target higher THM and HAA levels. The Drinking Water Committee believes that the proposed standard monitoring program (SMP) for sub-part H systems serving more than 10, 000 people, in which 8 samples are collected at 2-month intervals, is reasonable. The Committee does recommend, however, that the 8 samples be re-allocated so that, for both free chlorine and chloramines, 3 samples be taken at potential high THM sites, 3 samples be taken at potential high HAA sites, and only 1 sample be taken at an average site and at the point of entry to the system. If indeed the objective is to locate and monitor the sites with high THM and HAA concentrations, more samples need to be allocated to this objective. One point of entry site is sufficient to gauge the initial concentration of THMs and HAAs entering the system, and only one "average" site should be sufficient to maintain connectivity to the existing compliance monitoring program. The Committee also believes that the "average" site for the IDSE should be one of the average locations in the existing Stage 1 DBP compliance monitoring program. There is no reason not to allow this. It would mean that every 6 months (twice during the IDSE), utilities would only have to take 7 samples as part of the IDSE, with the eighth sample being one of the compliance monitoring samples.

The Committee further believes that the IDSE should require the measurement and reporting of residual chlorine (free or combined) concentrations at the time of DBP sample collection, and that individual THM and HAA species be reported in addition to the aggregate THM4 and HAA5 concentrations. It is also suggested that the IDSE recommend that pH, temperature, and the heterotrophic plate count be measured and recorded. Such information will prove to be valuable to the utilities, the primacy agencies, and the EPA in the future.

With respect to time of sample collection, there is no reason to believe that THM or HAA levels will be highest in the morning. In view of the dynamic and highly complex nature of water distribution systems, it is equally likely that THM or HAA levels at some locations will be highest in the evening. The Committee recommends that the reference to time of sample collection be omitted from the Guidance Manual (e.g. p. 2.9 of Guidance Manual) and be left to the discretion of the utilities and their respective primacy agency.

We believe that EPA needs to provide more guidance to the utilities with respect to identifying potential sampling sites with the highest HAA concentrations. P. 5-18, line 39 is the only reference in which some guidance is provided, although the guidance is not especially clear. It might be expected that, at least in waters with temperatures supporting microbial activity, HAA levels may decrease when free chlorine residuals decrease below 0.2-0.3 mg/L or combined chlorine residuals decrease below 0.5 mg/L.

This may not be the case in cold waters in which microbial activity is minimal; in such cases, high HAA sites may coincide with high THM sites. Distribution system dynamics, water age, chlorine residual data, and heterotrophic plate count data should be examined in selecting sample sites.

The Guidance Manual should indicate that selection of SMP monitoring sites must be justified rather than simply recommending that they be justified (p. 1-4, line 14), and that the IDSE report must (rather than should) provide justification for the selection of sites (p. 5-24, line 16).

The Drinking Water Committee believes that the proposed system specific studies (SSS) approach described in Chapter 6 needs improvement if sound guidance is to be provided to the utilities. Water consumption (demands) should be more accurately simulated in the network model, given the available information. It is important to realize that different types of water users will use water at different times and rates during the day. Water demands should be classified and allocated based on their water use type (domestic, industrial, commercial, etc.) and each type of water user should be assigned an individual water use pattern over a 24-hour (or other) period. Accurate demand distribution could be obtained using land use information or using water meter or assessor's parcel number location (geocoded meter location). The land use computation method consists of intersecting demand area polygons with land use polygons and water duty factors to create water demands for selected analysis nodes. The geocoded meter location method consists of grouping water billing data into demand areas around analysis nodes by using a spatial reference of water meters, yielding an accurate demand distribution as demands are allocated per customer billing accounts (and automatically taking into account vacant parcels and large water users).

Other considerations

Major

1. The terminology TTHMs (total trihalomethanes) to represent the four bromine- and chlorine-containing THMs is no longer appropriate. Now that researchers and EPA scientists are beginning to measure iodinated THMs in finished drinking water, regulations that pertain to only the four bromine- and chlorine-containing THMs should refer to these as THM4. A precedent for this form of nomenclature already exists, e.g. HAA5, HAA6, HAA9.

2. A number of assumptions and policy decisions were made with regard to development of the form of the Stage 2 DBP Rule and the IDSE, and these need to be stated at the outset and made clear throughout the Rule. These include:

- a decision to continue to regulate THMs and HAAs collectively as group parameters rather than as individual species;

- a decision to continue to regulate only five of the HAAs (HAA5) rather than all

nine bromine- and chlorine-containing HAAs (HAA9);

- recognition of the fact that, for purposes of simplicity, the IDSE overlooks short-term temporal variability in the selection of sites for locating and monitoring maximum levels of THMs and HAAs;

- recognition of the fact that sampling and monitoring costs were key considerations in designing the requirements for the standard monitoring program for the IDSE;

- recognition of the fact that, although the SWAT model was developed for modeling the effects of treatment on DBP formation and was not developed to model changes in THM and HAA concentrations in distribution systems, it was the only tool that the EPA had for purposes of the benefits analysis in support of the Stage 2 Rule.

3. The SWAT model is used in the benefits analysis to predict monthly DBP concentrations both under current conditions and under conditions where plant modifications have been made to meet the requirements of Stages 1 and 2 (sections 3.7.2 and 5.4.1.1). This use of the model would be appropriate and extremely valuable if it could be relied upon for good predictions in such applications. Unfortunately, that is not the case. Large discrepancies exist between SWAT results and ICR data, raising serious questions regarding either the accuracy of the SWAT model or the adequacy of attempts to characterize DBP concentrations of dynamic systems with so few samples (four sites with four samples per year). Two aspects of data presentation in the Stage 2 DBPR Economic Analysis served to greatly under-represent the discrepancies -- (1) the use of cumulative frequency distributions (pages 3-31 and A-18 through A20), and (2) miscalculation of "mean predicted errors" (page A-34 and Exhibit A.21). The problem with the use of cumulative frequency diagrams is that such plots have the same shape even when paired values have little agreement. Plants with low THM4 or HAA5 from the SWAT model are not necessarily the same plants with low THM4 or HAA5 plants from the ICR data. This discrepancy is totally lost when the data are presented as cumulative frequency curves. In the calculation of the "mean predicted error," the absolute value of "SWAT annual plant mean – ICR annual plant mean" should have been used instead of signed values, or an R^2 value should have been calculated. The way the calculation was done, positive deviations cancelled out negative deviations thereby grossly underestimating "mean predicted errors." The graphical results of pages A-23 to A33 convey a much greater sense of the discrepancies between the SWAT model and the ICR data. The magnitude of these discrepancies raises many questions regarding subsequent use of either SWAT or ICR data in Economic Analyses or risk benefits calculations.

The limitations to the model's accuracy arise from the inherent limitations of the existing state of the art for predicting DBP concentrations from water quality data and/or the inherent limitations in the available database, and hence cannot be easily fixed. Under the

circumstances, the contribution that the model can make to an evaluation of the benefits of the Stage 2 rule is marginal at best. We recommend that either this portion of the analysis of the benefits be eliminated or that the presentation should be altered to reflect the very limited accuracy of the model, and also to correct the flaws claims in the current justification for its use.

Minor

1. It should be made clear, in all documents relevant to the Stage 2 Rule, that quarterly monitoring of DBPs means every 3 months. For example, Table 5.4 and page 192 do not indicate that the basis for the LRAA calculation is sampling at 3-month intervals rather than once each quarter as in the current THM Rule and Stage 1 Rule.

c) Long Term 2 ESWT Rule; ***Cryptosporidium*** **Occurrence Subgroupence**; Dr. Rhodes Trussell, Dr. Michael Daniels

In this section, we will discuss the stochastic modeling of the potential benefits of these new drinking water regulations. Roughly, we can think of this model as containing three pieces. The first piece models the concentration of cryptosporidium in source water. Bayesian hierarchical models are used to model the concentrations. Such models easily accommodate many complex features seen in this data, including low recovery probabilities, the presence of false positives, and the presence of true cryptosporidium free source waters. The second component of the model considers the distribution of treatment effectiveness as a function of true concentration. The first assumption made here is that treatment effectiveness is independent of concentration. Based on expert opinion, treatment effectiveness across the nation is assumed to follow a simple triangular distribution. Some discussion of this piece of the model is contained in the "Toolbox" section. The third piece of this model considers the distribution of infectivity (and illness) conditional on both concentration and treatment effectiveness. A Bayesian hierarchical model is also used here to model the distribution of infectivity across strains. A discussion of this third piece of the model is contained in the 'Risk assessment' section and below. For the first and third pieces of the model, Markov chain Monte Carlo (MCMC) methods are used to sample from posterior distributions which are used to both estimate parameters in the model and to address the uncertainty associated with these parameters. In complex Bayesian models, MCMC is the only way to do this. We will now discuss some specific issues regarding the first piece of the model, the national occurrence distribution of cryptosporidium.

First, the occurrence modeling appears to be both plausible and well-done. However, we would like to see the following issues addressed, either by supplementing the current documents and/or modifying the model. A key component in Bayesian hierarchical models is specification of prior distributions, which a priori, characterize the state of knowledge about the parameters at the higher levels of the model. Little information is contained about these priors in the current documentation and it appears that the sensitivity of the occurrence distribution and the infectivity parameter, k, to these priors

has not been assessed. Sensitivity analyses should be conducted and documented. Particular care should be taken to avoid using the data to specify the prior distribution. In doing this, the data is being used 'twice' and the amount of uncertainty is thus underestimated. The parameters that we are most concerned about are the variance in the infectivity model which characterizes the variability between strains since we only have 2 strains with which to estimate it, and the parameters in the occurrence models which characterize the variability of the spatial, temporal, and residual random effects. In addition, the use of prior distributions for other parameters in the model should be documented.

Another issue which needs to be addressed is the computation of the average concentration by plant for the 18 month data. Averaging equally over the 18 months to obtain an annual average will only give us an unbiased estimate of the true annual average if there are no seasonal effects. Otherwise, we are counting six months twice in the averaging. During discussions during the meeting, it was stated that parameters charactering seasonality were including in the model (in the form of the turbidity term). A way to fix this problem, would be to first average the data by month, and then to use the mean of the twelve monthly averages that result as the annual average.

The current report includes some model-checking using the estimated distributions of true concentrations, but we would like to see some additional model checking. In particular, we would like to see an additional internal check and an external check. The internal check will use the current output from the MCMC sampler to sample from the distribution of predicted oocyst counts (Y's) (from the posterior predictive distribution of Y) . To assess how consistent predictions from the model are with the observed data, about twenty sample distributions can be plotted versus the observed distribution of counts. The observed distribution ideally should lie within these 20 and should look similar. For an external check, the current model could be fit to the first 12 months of the 18 month data, then months 13-18 could be predicted by the model and finally these predictions compared to the observed data.

There are some additional features that should be included in the document. A map of the sites for both the ICR and ICRSS data would be helpful to see how similar the distribution of sites was spatially across the surveys and to also look for spatial similarity in concentrations for sites close together and/or in the same regions of the country. In addition, a small paragraph documenting the convergence and mixing checks on the MCMC sampler. Finally, in the discussion of the model for the unfiltered plants, several parameters that were included in the filtered model are excluded, including turbidity. Justification for this should be documented.

A final point we would like to address is the approach to concisely summarize the occurrence distribution functions using parametric models, in particular the log normal. This was done to simplify computations for the individuals conducting the risk analysis. There should be documentation confirming that the realizations of the cdf's from the MCMC sampler were well approximated by log-normal cdf's. Second, several ad hoc

simplifications were done to sample the cdf's for the risk analysis (see bottom of p. 5-15 of the economic analysis document). These should be examined carefully for their plausibility and the conclusions documented.

We would like to conclude with a discussion of the large amount of uncertainty in the modeling here. For example, the occurrence distributions are 'estimated' based on only one year of data. If these distributions are stable over years this should be ok. However, the current data does not allow determination if the particular year in which the data were collected were aberrant (for example, due to weather patterns) or if there is some sort of trend in occurrence over time. In addition, for the infectivity modeling, the distribution of infectivity across strains is estimated based on only three strains which may or may not be a random sample of strains. The only way this distribution can be estimated is to make a strong assumption about its form, here log-normal. The ultimate accuracy of the predicted benefits from these stochastic models relies on both the representativeness and applicability of the observed data and the numerous modeling assumptions that were made in the course of the three pieces of the model discussed at the beginning of this section.

d) Long Term 2 ESWT Rule: Microbial Risk Assessment Subgroup; Dr. Ricardo De Leon

The Committee recognizes that it has very limited expertise in the area of quantitative risk assessment. Therefore, we recommend that the Crypto risk assessment that was included in the Economic Analysis for the Long Term 2 Enhanced Surface Water Treatment Rule be subject to additional review by recognized experts in this field such as Dr. Charles Haas, Dr. Peter Teunis, or Dr. Douglas Crawford-Brown. The Committee decided to examine and comment on the assumptions that were used in the risk assessment. Two criteria were considered in this evaluation:

1) Are the assumptions transparent?
2) Is there scientific evidence to support these assumptions?

Each of the basic elements of microbial risk assessment was examined in order: Hazard Identification, Dose-Response Assessment, and Exposure Assessment. Then the outcome of the risk assessment was evaluated. Because the whole risk assessment is quite complex, the Committee recommends that the document include a flow chart that shows how the different elements were derived. Exhibit 5.2 is helpful but does not go far enough. An additional figure is needed to show what elements were in the pre-regulation risk assessment vs. the post-regulation risk assessment and how the benefits of the proposed regulation were calculated.

A. Hazard Identification (pgs 5-7 - 5-8)

The Committee agreed with the basic information on Crypto health effects that were presented in this section. A few additional areas should be included here:

- What do serological studies indicate about the prevalence of cryptosoporidium exposure/infection in the US?

- Information on secondary transmission of Crypto. Haas et al. 1999 present data on prevalence of secondary cases of crypto from two outbreak investigations that ranges from 4 - 33%. CDC may have more information on this.

- Information on asymptomatic infections of Crypto. Asymptomatic infections play an important role in secondary transmission of infection. Information on the prevalence of asymptomatic Crypto infections by age should be included in the Hazard identification. This information has an impact on the estimated probability of illness given infection.

B. Dose-Response Assessment (pgs 5-9 - 5-14)

Dose Response Function

The general exponential model was used to model the dose-response relationship based on the data from three human challenge studies. Modeling this relationship is important for estimating the risk of infection/illness at low doses because it is not economical to conduct large human challenge studies at low doses to directly measure the risk at low doses. The rationale for using a model of the dose-response data should be explained in the document. The choice of the exponential dose-response model is reasonable and has been used in previous Crypto risk assessments (Haas et al., 1996, 1999). It is not clear if other models were considered and fit to the data from the human challenge studies.

It is not clear how infection was defined in these analyses. A table similar to that below would be helpful.

Oocysts detected in stool	**Symptoms (Illness)**	**Infected?**
Yes	Yes	Yes
Yes	No	Yes
No	Yes	Yes
No	No	No (but some asymptomatic infections may fall into this category if there is a low level of oocyst shedding)

For enteric pathogens, infection is usually defined as the detection of the pathogen in stool samples. However, evidence from the human challenge studies suggests that oocysts are not always detected by direct fluorescence assay (DFA) in challenged subjects who have symptoms compatible with cryptosporidiosis. So all challenged subjects who develop appropriate symptoms within the appropriate incubation period were often classified as infected in the human challenge studies. However, it is possible that, because the detection limit of DFA is quite high, there may be some individuals with asymptomatic infections that were not detected because they shed low levels of oocysts.

The Committee noted that it may be more useful to model illness rather than infection - WHY? (CHRISTINE IS NOT SURE SHE AGREES WITH THIS AND WANTS TO KNOW THE RATIONALE FOR THIS SUGGESTION) , Ric doesn't agree either, infection should be the endpoint because the course of illness is likely to be affected by prior exposure, health of individuals, and other possible factors.

Infectivity

NEED TO CLARIFY "VIABLE" VS. "INFECTIOUS" OOCYSTS. Viability is usually evaluated by evidence of dye uptake or excystation. Infectivity is usually defined as invasion and replication in a host cell, mouse model or human volunteers.

The Committee considered the two aspects of infectivity that were discussed in the Economic Analysis document (pg 5-10): a) the proportion of the total oocysts from the occurrence estimates that have internal structures and were considered infectious, and b) the infectivity of three strains of *C. parvum* that were used in the human challenge studies (IOWA, TAMU and UCP).,

Infectivity of oocysts in the environment: In the occurrence data, the EPA assumed that only a proportion ("v") of oocysts detected in the environment are infectious. This is discussed in more detail in section C. below. (SEE RHODES' EXPLANATION OF THIS)

Infectivity of oocysts in the dose in the human challenge studies: The analysis of the human dose-response data assumes that 100% of the oocysts in the dose were infectious. However, it is likely that not all of the oocysts in the dose were "infectious". Ric DeLeon discussed new data on cell culture infectivity and mouse infectivity that shows that approximately 5% of freshly excreted oocysts from a cow are "infectious" (see Upton et al., Rochelle et al., and Arrowood et al.,). It is important to clarify how the viability of the oocysts used in the dose was evaluated. Was this based on excystation rate or on the morphological appearance of intact oocysts? It would also be helpful to verify the time between oocyst excretion and dosing volunteers (<2 weeks?) because this may affect the proportion of infectious oocysts in the various doses.

Ric DeLeon suggests that the UCP data should not be included in the analysis because it is an outlier. The ID_{50} estimated from the human challenge studies is much higher for this strain than for the other two strains. Ric thinks this is because UCP has been passaged a lot and has become attenuated. Cell culture data with other strains indicates ID_{50}s of less than 100 oocysts. An ID_{50} of >1000 for the UCP strain appears to be an outlier. The effect of excluding the UCP challenge data would be to lower the estimate of infectivity, increase the estimate of risk and possibly increase the estimated benefits.

There are some major concerns with the models for infectivity across strains. Primarily, there are only two strains (assuming UCP will be excluded for reasons discussed above) to estimate the distribution of infectivity across strains. As a result, the distribution of

infectivity derived from fitting the model will rely very heavily on the assumed distribution of infectivity. We suggest using a mixture of two distributions for infectivity to help characterize this uncertainty. The first component of the mixture will be a lognormal distribution (with probability ½) and the second component will be a log-t distribution with three degrees of freedom (also with probability ½). The latter provides heavier tails and considers more extreme values for k to be more likely. The prior distribution for the variance parameter, sigma, which characterizes the variability of infectivity across strains, must be chosen carefully as well. Since there are only the two observed strains, the prior distribution on sigma, similar to the assumed distribution on infectivity across strains, will be highly influential on the posterior distribution of sigma (and k). The prior hyperparameters should not be chosen based on the variability observed in the strains as this will create a posterior with too little uncertainty (from using the data twice).

One limitation of the infectivity data from the human challenge studies is that currently only genotype 2 strains have been tested. A human challenge study with a genotype 1 strain is currently in progress and will provide valuable data for future Crypto risk assessments. When this data becomes available, the EPA should consider redoing this risk assessment with the new data. <u>One consideration with the data from this new study is that there may be more batch-to-batch variability in the dose because the only source of oocysts will be human hosts and the inoculum will not be passaged through cows</u>

<u>Infectivity data from cell culture studies</u>: The estimate of infectivity could include cell culture infectivity data because this would provide additional information. There seems to be some consistency between the cell infectivity data and human infectivity data (REF). Cell culture data suggests that most strains examined to date have an ID50 of less than 100 oocysts.

<u>Variability in host susceptibility and the effect of previous infections:</u> Variability in host susceptibility was not considered in the analyses of infectivity and morbidity. This could be a significant source of variability that EPA should consider incorporating into this risk assessment. The agency should consider consulting with Dr. Chappell about what is known on host susceptibility from her studies and Dr. Teunis about how he incorporated this into his analyses of the human challenge study data. The analysis assumed that the population had no previous immunity to Cryptosporidium. It is likely that the volunteers in the human challenge study are a mix of naïve and previously exposed individuals, and that differences in host susceptibility and previous immunity had an effect on the estimates of the dose-response parameter "k".

Morbidity Rate (pg 5-12)

The morbidity rate was defined as the probability of illness given infection and was estimated using a triangular distribution based on a range from Haas et al 1996. This rate may not be accurately estimated if asymptomatic infections were not detected in the human challenge studies. The greater the rate of asymptomatic infections, the more the

probability of illness given infection will be underestimated.

In addition, the probability of illness given infection may be underestimated because this data is based on challenge of healthy adult volunteers. In the whole population, there may be a greater probability of developing illness given infection because the whole population includes sensitive sub-populations that are more likely to develop symptomatic illness given infection.

Individuals with existing antibodies to Cryptosporidium may have a lower morbidity rate. However, data from Okhuysen et al., (1998) does not support this. The document does point out that this experiment was conducted at relatively high doses, and there is no data on the morbidity rate at low doses in a population with previous Cryptosporidium infection.

Mortality Rate (pg 5-13)

Ric DeLeon pointed out that the mortality rate in AIDS patients that was used in this analysis is based on old data from the 1992 Milwaukee outbreak. Current AIDS therapy has reduced Cryptosporidium mortality in AIDS cases so the mortality rate in this analysis may be too high. Or the mortality rate derived from Milwaukee may be too low for populations with a greater proportion of AIDS patients. The document does explain that the mortality rate may be dose dependent and there is no data to support this hypothesis.

C. Exposure Assessment (pgs 5-14 - 5-24)

Exposure assessment in this analysis included estimation of:

- the distribution of total and infectious Cryptosporidium oocysts in finished water - derived from source water levels and estimated removal/inactivation from treatment

- the population served by systems potentially affected by the LT2ESWTR

- the distribution of individual daily average drinking water consumption

1) Distribution of total and infectious Cryptosporidium oocysts in finished water

Source Water Concentrations

This issue is addressed by a separate sub-group.

Infectious Cryptosporidium Oocysts (pg 5-16)

The proportion of Crypto oocysts in the environment that are infectious was estimated

from the ICR and ICRSS data based on morphological appearance of oocysts and the proportion of oocysts with internal structures. The EPA analysis also used data on infectivity from a study by LeChevallier. This data was expressed as a distribution with a range of 30-50%, mode = 40% (page 5-17). There is some evidence that PCR detection of Crypto DNA in cell culture (method used by LeChevallier) will give false positives because some oocysts may not be infectious but it is still possible to detect their DNA. This method picks up the oocysts that stick to the cell monolayer even if they have not infected the cells (EPA report by DeLeon and Rochelle) There appears to be a need for more peer-reviewed data in this area. The assumptions about the proportion of infectious oocysts in the environment determine the variable "v" used in the risk analysis equation $P_M = M \times (1-[\exp((-C*v*I)/k)]^n)$

Pre-LT2ESWTR Removal/Inactivation of Cryptosporidium (pg 5-17)

The risk assessment was based on estimated Crypto levels in finished water. These levels were estimated by source water values from ICR and ICRSS and assuming a certain log removal of Crypto (2-5 logs with mode of 3 logs - based on studies of actual water treatment plants). But problem that Aboytes study contradicts this - and suggests that EPA's assumption of removal is too high and that there are 10-fold higher levels of crypto in finished water than predicted by EPA. Problem is that Aboytes (2000) study is based on cell culture-PCR detection and may overestimate crypto detection in finished water.

Post- LT2ESWTR Removal/Inactivation of Cryptosporidium (pg 5-18)

COMMENTS ON THIS FROM THE TOOLBOX SUB-GROUP?

Water consumption estimates (pg 5-22)

Why were two distributions of consumption used? What is the difference between them? Why are the median values (1.045, 0.71) lower than previous estimates of daily water consumption? Why was Distribution 1 was used for the main analysis and Distribution 2 used in the analysis in the appendix? THE COMMITTEE NEEDS TO REVIEW THE PREVIOUS EPA SAB REVIEW OF THIS CONSUMPTION STUDY.

It is not clear how the daily estimated consumption was extrapolated to annual exposure in Exhibit 5.8 (pg 5-23). Is individual consumption split between CWS and NTNCWS based on the estimated proportion of their time spent at home and at work or school or are individuals counted in both categories - i.e. total consumption counted twice. This estimate could be refined by age group. The very young and very old are likely to consume exclusively CWS water and these are the most vulnerable age groups.

D. Risk Model Structure

RHODES was working on an explanation of what "v" is in the risk estimate equation

$P_M = M \times (1-[\exp((-C*v*I)/k)]^n)$

Maybe should express "v" as a ratio:

Percent of infectious oocysts detected in the environment/ percent of freshly excreted infectious oocysts in the inoculums used in the human challenge studies

E. Results of the Risk Assessment

Estimates of Risk - The EPA needs to compare these results to previous crypto risk assessments by Haas, Rose, Perz and Teunis. A review of these previous studies (including the sources of data, assumptions and statistical methods) should be added to the preamble.

The document should include a summary discussion of uncertainty and variability that is more detailed than what is presented on pg 5-26. This discussion should include the following:

- Identifying sources of uncertainty (already included on pg 5-26)

- Magnitude of uncertainty

- Effect of uncertainty on the estimate of risk

- Sensitivity analysis of what sources of uncertainty have the greatest impact on the estimate and the implications of this for future research efforts

  – (Messner says it is dose-response data. Uncertainty in benefits was driven by dose-response data. Uncertainty in cost was driven by occurrence data. Cost stems from how the systems are classified into bins where they need to take action.)

- Identifying sources of variability (already included on pg 5-26)
Sources of oocysts may be different for different communities (watersheds)- animal sources vs human sources

  – Magnitude of variability
  – Effect of variability on the estimate of risk
  – Sensitivity analysis of what sources of variability have the greatest impact on the estimate

The document should also include a discussion of what assumptions may lead to an underestimate or overestimate of the risk and the benefits of the proposed regulation.

For example, because the analysis only considered morbidity and mortality as outcomes, it is possible that the benefit is underestimated because the benefit of avoided infection was not considered. Avoiding infection in the community will reduce the potential for secondary transmission and additional cases and deaths. From a public health perspective, infection is the key outcome.

The Committee suggested that the EPA also try a "worst case scenario" using worst case for everything but don't do extensive Monte Carlo analysis in this risk assessment. This could then be compared to the risk assessment that uses best scientific judgement.

Worst case scenario:

- Assume greater water consumption?
- Assume finished water Crypto oocyst levels from Aboytes et al. (2000) study
- Assume that 50-100% of detected oocysts are infectious
- Assume that infectivity of oocysts is like that of the TAMU strain
- Assume that 20% of population is sensitive and more susceptible - ie higher morbidity and mortality

e) Microbial Toolbox Subgroup; Dr. L.D. McMullen

The Drinking Water Committee commends the EPA as well as the FACA stakeholder process for their development of the bin classification and microbial toolbox. These alternatives add great flexibility to the rule for meeting varying water quality and treatment options with the result of providing safe drinking water to the citizens of the United States.

The Agency's charge to the committee was to look at four of those toolbox options: 1) off stream raw water storage; 2) pre-sedimentation, 3) lime softening and 4) lower finished water turbidity.

The data utilized by EPA in determining the appropriate credit for off stream storage are derived from experiences in the United States as well as other peer-reviewed literature from elsewhere in the world. The data show that there is variability in the removal of active oocysts in different reservoirs, due primarily to sedimentation, but also due to inactivation within the environment, both of which are governed to some degree by temperature. After reviewing the supporting documentation, the Committee does not feel there is adequate data to demonstrate the proposed credits for off stream storage and therefore recommends that no presumptive credits be given for this toolbox option. However, the Committee agrees that a particular utility should be able to take advantage of this removal by sampling after the off stream storage for appropriate bin placement.

With regard to pre-sedimentation, many water treatment plants located on highly variable surface waters utilize pre-sedimentation as a treatment technique to remove large quantities of suspended material prior to input to an existing conventional treatment plant or lime softening operation. The real purpose of the pre-sedimentation is to provide for more consistent water quality prior to the conventional or lime softening treatment plant. In reviewing the literature provided by the Agency, not only on *Cryptosporidium*, but also on spore removal with both pilot as well as full-scale plants, it seems that the data are minimal to support a 0.5 log presumptive credit for pre-sedimentation. As a result, the Committee feels that no credit should be given for pre-sedimentation. Additionally, the Committee feels performance criteria other than overflow rate need to be included if credit is to be given for pre-sedimentation. As with off stream storage, the Committee does agree that a utility should be able to take advantage of this removal by sampling after the pre-sedimentation treatment process for appropriate bin placement.

EPA proposes a 0.5 log credit toward *Cryptosporidium* treatment with lime softening plants that utilize two-stage softening. Based on the data provided, it appears that a 0.5 log of additional *Cryptosporidium* removal is an average number for a two-stage lime softening plant. Based on the data, single stage as well as two-stage lime softening generally outperforms conventional treatment due primarily to the heavy precipitation that occurs in lime softening reactors particularly when magnesium precipitation occurs. By treating water through a second precipitation reactor, additional removal efficiencies should occur. However, depending on how the second reactor is utilized and the chemical feeds to the secondary reactor, the removal efficiencies vary significantly as presented in the literature. Therefore, the Committee supports a 0.5 log additional removal for two stage lime softening if all the water passes through both stages. If a portion of the water is bypassed around the first stage, the Committee feels there should be no additional removal credit given.

Finally, the additional credits for lower finished water turbidity seem to be consistent with what is known in both pilot and full-scale operational experiences for *Cryptosporidium* removal. As was contained in Enhanced Surface Water Treatment Rule, lowering effluent turbidity in the treated water results in lower concentrations of *Cryptosporidium*. Therefore, it would be consistent to assume that even further lowering of turbidity would result in further reductions in *Cryptosporidium* effluent from filtration processes. It is also logical to assume that individual filter effluent turbidity meeting a specific criterion will provide for better water quality than for combined filter effluent meeting the same requirement. However, limited data were presented to show the exact removal that can be achieved using these two operational benchmarks. Based on the data provided, the Committee recommends that a 0.5 log credit be given to plants that demonstrate a turbidity level in each individual filter effluent (IFE) less than or equal to 0.15 NTU in at least 95 percent of the measurements taken each month. No additional credit should be given to plants that demonstrate a combined filter effluent turbidity of 0.15 NTU of less.

OTHER ITEMS

The Committee's understanding of the approach used in developing the microbial toolbox is as follows. The additional log removals in the table of bin requirements are based in part on the assumption that conventional filtration plants in compliance with the IESWTR achieve an average of 3 logs removal of *Cryptosporidium*. It is the Committee's understanding that this assumption also indicates that all conventional treatment plants can be expected to remove a minimum of 2 logs removal of *Cryptosporidium*. Furthermore, it is the Committee's understanding that an objective of the rule is to achieve an average oocyst concentration in treated surface waters of 10^{-4} oocysts/l or lower. Given the oocyst concentrations in bins 2,3,and 4, and considering an average removal of 3 logs for conventional treatment, the additional removal requirements in bins 2,3,and 4 are expected to provide an average treated water oocyst concentration of 10^{-4} oocyst/l or lower.

This approach differs from past approaches to *Giardia* and *Cryptosporidium* treatment credits and from present approaches to *Giardia* control. Current regulations for *Giardia* control provide 2.5 logs of removal credit when conventional treatment is used. It is the understanding of the Committee that this removal credit for *Giardia* is based on the minimum removal (not the average removal) achieved by these plants.

These differences between the ESWTR and LT2ESWTR regulations in the bases for assuming removal credits for *Giardia* and *Crypotosporidum* are not readily apparent and should be clarified and justified in the new regulations. Appropriate guidance will be needed for implementation of these two regulations.

11. Public Comment

Dr. Paresh, Los Angeles Water District requested time to make a comment as a member of the public. He thanked the Panel for the open proceedings on this issue. Dr. Paresh noted the complexity of the situation for large systems with blended water supplies. He asked for EPA to do whatever it could do to allow states flexibility to address issues on a case by case basis.

12. Dr. Trussell adjourned the meeting.

I certify that these minutes are accurate to the best of my knowledge.

/ S /	**/ S /**
Dr. R. Rhodes Trussell	Mr. Thomas O. Miller
Chair	Designated Federal Officer
EPA SAB Drinking Water Committee	EPA SAB Drinking Water Committee

Attachments:

A FR Notice; Vol. 66, No. 217; 56557; November 8, 2001
B Panel Roster
C Panel Charge
D Panel Bios
E Sign in Sheets
F Dr. Singer's Handouts
G Compilation of meeting comments